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EXAMINER

LUDLOW, JAN M

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,399

Applicant(s)

LACOURT ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-43,45-49,51-56,58-60 and 74-82 is/are pending in the application.
- 4a) Of the above claim(s) 15-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-14,41-43,45-49,51-56,58-60 and 74-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/30/2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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1. Claims 1-14, 41-60, 74-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the limitation beginning "each of said sealed metering tips..." is unclear because the plurality of metering tips has not been positively recited (the positive recitation was deleted in the amendment). Currently, claim 1 requires only two structural elements: a plurality of first tip retaining stations and a plurality of second tip retaining stations. A common tip rack having four or more holes in it would satisfy these claim limitations. Claim 41 is similarly limited only to two sets of tip retaining stations and a housing, the remainder of the claim being directed to intended use. Claim 52 is unclear because it is unclear whether or not "said chemistry systems" are positively recited. Note that claim 52 limits the analyzer, which is not a positively recited element of the invention. In claim 55, "said optical testing means" lacks antecedence. In claim 75, "a said first retaining position" is unclear. Claims 76-79, 81-82 are all directed to intended use and/or method steps and are therefore unclear as to how they limit the structure of the instant **apparatus** claims directed to a buffer or auxiliary supply alone.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

2. A person shall be entitled to a patent unless –

3. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

6. Determining the scope and contents of the prior art.
7. Ascertaining the differences between the prior art and the claims at issue.
8. Resolving the level of ordinary skill in the pertinent art.
9. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 3, 6-7, 41-43, 74-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Samsoondar (WO 99/47261).

12. Samsoondar (WO 99/47261) teaches a blood analyzer apparatus having a sample handling means, e.g., 94 carrying sealable tips 1,2, in stations 90, sealing means 5, spectrophotometer 14 and smaller tips 4 for insertion into the sealable tips.

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Note that stations 90 are structurally capable of carrying either sealed or unsealed tips, and therefore satisfy the limitations to first and second pluralities of tip retaining stations as claimed. Note that the detector is structurally capable of detecting an absent tip, and that the conveyor removes tips from the detector housing. Note that the apparatus is structurally capable of the intended use recitations of claims 76-19, 81-82. Note with respect to claim 41, "said buffer acting..." is a statement of intended use and not given patentable weight. Note that the chemistry systems are not claimed. The recitation "A buffer for interconnecting..." has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

13. Claims 1, 8, 41, 76-79, 81-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Corbett (WO 92/20776).

14. Corbett teaches ring 14 with stations 12 for supporting heat-sealed pipette tips. Note that stations 90 are structurally capable of carrying either sealed or unsealed tips, and therefore satisfy the limitations to first and second pluralities of tip retaining stations as claimed. Note that the detector is structurally capable of detecting an absent tip, and that the conveyor removes tips from the detector housing. Note that the apparatus is structurally capable of the intended use recitations of claims 76-79, 81-82. Note with

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respect to claim 41, "said buffer acting..." is a statement of intended use and not given patentable weight. Note that the chemistry systems are not claimed. The recitation "A buffer for interconnecting..." has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

15. Claims 4, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samsoondar as applied to claims 1, 41 above, and further in view of Corbett.

16. Samsoondar fails to teach heat sealing.

17. Corbett teaches a method for sealing pipette tips for use as containers by heat-sealing as described above.

18. It would have been obvious to use a heat sealer in the device of Samsoondar in order to use an art recognized method of sealing tips for use as containers as taught by Corbett.

19. Claims 3-4, 42, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett as applied to claims 1-2, 41 above.

20. Corbett fails to explicitly teach apparatus for heat sealing.

21. It would have been obvious to provide a device to perform the heat-sealing step of Corbett in order to perform the method as described.

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22. Claims 1, 3-4, 6-14, 41-43, 45-49, 51-56, 58-60, 74-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs *et al* (USP 5,846,492) in view of Corbett and/or Samssoondar.

23. Jacobs *et al* teach a sample-metering device in a clinical analyzer with a sample handling apparatus 20 having a plurality of sample containers 19 containing sample; a sample metering apparatus having a proboscis 46, metering tip 48 supply in ring 20, a metering pump 71; a sample processing apparatus 30 having one or more test elements E. An air tube 100 may be applied to the bottom of the tip to prevent leakage (col. 5, lines 15-25). The primary analyzer cycle method comprising: attaching a tip to the proboscis to create the metering assembly; moving the metering assembly to immerse the tip in the sample and aspirate sample from the sample container; moving the metering assembly to a dispense the sample liquid on to the test element; the test element is linearly transferred to an incubator (not shown) within which it is read or detected at a test station 146 (column 8, lines 10-18). Then, Jacobs *et al* teach performing a secondary quality cycle comprising measurements of the sample through-the-tip 48 at the NIR via spectrophotometer 110 at station 82 (column 5, lines 1-30).

Note: the reference teaches the sample liquid can be deposited on the test slide before the through-the-tip analysis (column 8, lines 23-27).

24. Jacobs *et al* do not teach a sample handler for holding sealed tips.

25. The teachings of Samssoondar and Corbett are given above.

26. It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the apparatus of Jacobs *et al*, a holder and sealer

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for the pipette tip of Corbett *et al* in order to allow for efficient transfer of the sample and provide time savings and avoidance of sample contamination (page 3, lines 14-20) or a holder and sealer for the pipette tip of Samsoondar in order to provide known sealing means and conveyance as taught by Samsoondar and/or Corbett in place of air pressure 100 to maintain liquid in a pipette tip for reaction and/or measurement in the tip.

27. Claims 1, 3-4, 6-14, 41-43, 45-49, 51-56, 58-60, 74-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs *et al* (USP 6,797,518).

28. Jacobs teaches a supply of unsealed tips (col. 4, lines 60-61), e.g., in a tray (col. 5, line 37), aspirator 22, 52, heat sealer (col. 6, lines 41-43), optical detector 68, and tip removing means (col. 3, lines 9-10). Sealed tips can be used as containers to take samples for wet chemistry or dilution (col. 7, lines 44-52). Dry chemistry is also provided.

29. Jacobs fails to explicitly teach a plurality of sealed tip retaining stations.

30. It would have been obvious to provide plural sealed tip retaining stations to use the sealed tips to supply a wet chemistry or dilution station as described by Jacobs in order to use a structure analogous to the sample holder ring 32 of Jacobs. It is the examiner's position that a supply tray for plural unsealed tips inherently includes plural tip retaining stations. It would have been further obvious to form the tray as a ring analogous to the incubator 56 and sample holder 32 of Jacobs. Note that the detector is structurally capable of detecting an absent tip, and that the conveyor removes tips from the detector housing. Note that the apparatus is structurally capable of the

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intended use recitations of claims 76-19, 81-82. Note with respect to claim 41, "said buffer acting..." is a statement of intended use and not given patentable weight. Note that the chemistry systems are not claimed. The recitation "A buffer for interconnecting..." has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

31. Alternatively, claims 1, 3-4, 6-14, 41-43, 45-49, 51-56, 58-60, 74-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs *et al* (USP 6,797,518) in view of Samssoondar.

Jacobs teaches a supply of unsealed tips (col. 4, lines 60-61), e.g., in a tray (col. 5, line 37), aspirator 22, 52, heat sealer (col. 6, lines 41-43), optical detector 68, and tip removing means (col. 3, lines 9-10). Sealed tips can be used as containers to take samples for wet chemistry or dilution (col. 7, lines 44-52). Dry chemistry is also provided.

32. Jacobs fails to explicitly teach a plurality of sealed tip retaining stations.

33. Samssoondar teaches a system similar to that of Jacobs. Sealed tips are passed along a conveyor past the detector (Figure 1).

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34. It would have been obvious to provide plural sealed tip retaining stations in order to pass the sealed tips by a detector for analysis as taught by Samsoundar. It is the examiner's position that a supply tray for plural unsealed tips inherently includes plural tip retaining stations. It would have been further obvious to form the tray and/or conveyor as rings analogous to the incubator 56 and sample holder 32 of Jacobs. Note that the detector is structurally capable of detecting an absent tip, and that the conveyor removes tips from the detector housing. Note that the apparatus is structurally capable of the intended use recitations of claims 76-19, 81-82. Note with respect to claim 41, "said buffer acting..." is a statement of intended use and not given patentable weight. Note that the chemistry systems are not claimed. The recitation "A buffer for interconnecting..." has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

35. Applicant's arguments filed February 11, 2005 have been fully considered but they are not persuasive.

Applicant has not argued the rejections over Samsoundar and Corbett. Note that the instant claims are not the same in scope as the combination of the cancelled claims not previously rejected over these references.

Note that the instant claims do not actually require either the sealed or unsealed tips or the analyzer, despite repeated reference to the properties, functions, and intended method of use of these unclaimed elements.

Applicant argues that the instant claims have been amended to point out essential differences between Jacobs in view of Samsoundar and Corbett, but the instant claims have been broadened, not narrowed, by the instant amendment. Copious statements of intended use in the claims fail to limit the structure of the buffer itself, which, as noted by the examiner above, is only limited to two sets of plural retaining stations in claim 1, with the addition of a housing in claim 41, reading on a tip rack with four or more holes in it (rack = housing, two holes = first plurality of retaining stations, two holes = second plurality). Before the examiner can give weight to the sealed tips, unsealed tips and/or analyzer structure, they must actually be claimed elements of the invention, not merely elements intended to be used with it.

36. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on June 30, 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
September 5, 2005